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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,845	10/29/2003	Steven Savage	1105-003US02	7833
28863 7590 07/10/2008 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125				
EXAMINER				
GRAY, PHILLIP A				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
07/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplaw.com

Office Action Summary**Application No.**

10/695,845

Applicant(s)

SAVAGE ET AL.

Examiner

Phillip Gray

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 36, 37 and 39-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 17-19, 36, 37 and 39-44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO-SB06)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to applicant's communication of 4/10/2008. Currently amended and newly added claims 17-19, 36-37, and 39-44 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 4/10/2008 have been fully considered but they are not persuasive. Applicant's argue that the prior art fails to show "a plurality of openings that are each angled towards the proximal end of said tubular structure..." as in the newly amended claims.

Examiner is of the position that this is taught and shown in the prior art. Examiner draws applicant's attention to figures 13, 14 and 16 of Sandimore (see elements 100) for embodiments which satisfy and disclose the claimed limitation.

Further applicant's remarks argue that the prior art fails to teach or show "openings...that are arranged such that forces resulting from fluid flow out of said openings and out of said elastic restrictor are substantially balanced during performance of said medical procedure".

Applicant is reminded that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Under these guidelines examiner is giving a broad reading to the term

"substantially balanced". Examiner is reading "substantially balanced to mean "being in harmonious or proper arrangement or adjustment, proportion, etc",

It is Examiners position that, in the very least the Sandimore device (and openings/restrictor) is laterally/latitudinally balanced (see figure 16 and how openings/restrictor appear to be around the entire circumference of the device and thus would displace forces equally out of two opposing sides and also the entire circumference of the device). Examiner is using these as examples of satisfying the claim language.

If applicant has a different "balance" of forces or a specific definition of the term balance which they wish to incorporate applicant is recommended to amend the claims to include this.

The elements disclosed in the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19, 36-37, and 39-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sandmore et al. (U.S. Patent Number 6,059,760).

Sandmore discloses a cannula (catheter) having a reverse flow tip (see figures 1-3 and 12-19). Sandmore discloses a catheter for use in a medical procedure, with an elongate tubular structure (36, 46, 38, 45, 28) (fully capable of meeting the size, flow rate), elastic restrictor, and plurality of stem section hole openings formed on the side walls (see elements 100 of figures 12-19) angled toward the proximal end of the catheter for a retrograde fluid stream.

It is examiners position that it is inherent and/or implicit in Sandmore that the tubular structure on the tip section has elastic restrictors that are fully capable and would change size in response to a change in fluid flow (increase in fluid flow) which would provide a variable amount of fluid force restriction. It is examiners position that the tubular structure on the tip section (as in figure 13) contains openings (100 and/or 132) which are made of an elastic material and whose shape would increase if a large volume or high velocity of fluid were to flow out of these openings. These openings, because of the material of which they are made from, and the structure and orientations of them would be fully capable of satisfying the claimed limitations of the elastic restrictor. Similar to how a hole in a water balloon would increase if squeezed or water pressure increased (water balloon with hole attached to a faucet). The fact that the structure exists and is made of an elastic material would be evidence of this structure and capacity to perform this function. It is examiners position that the openings would be fully capable of all structural, functional, operational and spatial limitations as currently amended in the claims.

In the alternative if not inherent or obvious from Sandmore alone, Claims 17-19, 36-37, and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandmore in view of Jones et al. (U.S. Patent Number 5,843,050).

Sandmore discloses a cannula (catheter) having a reverse flow tip (see figures 1-3 and 12-19). Sandmore discloses a catheter for use in a medical procedure, with an

elongate tubular structure (36, 46, 38, 45, 28) (fully capable of meeting the size, flow rate), elastic restrictor, and plurality of stem section hole openings formed on the side walls (see elements 100 of figures 12-19) angled toward the proximal end of the catheter for a retrograde fluid stream.

If the openings of Sandmore (as disclosed above) do not satisfy the claim limitations requiring an "elastic restrictor" it would be an obvious modification to have an elastic restrictor on the Sandmore tubular structure. Sandmore discloses the claimed invention except for the elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction. Jones teaches that it is known to use an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction (as set forth beginning with paragraphs at column 11 line 14 through 63 for example and shown in figures 5 and 7) to provide a way to control fluid flow through the catheter by minimizing fluid flow in the opposite direction or permit the escape of pressurized fluid media. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter as taught by Sandmore with an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction as taught by Jones, since such a modification would provide the catheter with an elastic restrictor that changes in size in response to a change in fluid flow which provides a variable amount of fluid force restriction for providing a way to control fluid flow through the catheter by minimizing fluid flow in the opposite direction or permit the escape of pressurized fluid media.

Further, concerning the other claim limitations, Sandmore discloses a hub section (42), a shaft section (36), and a stem section (22), and distal tip with a small opening comprising an elastic restrictor (138,100) and is fully capable, or in the alternative an obvious configuration to one of ordinary skill in the art, of providing a variable amount of fluid force restriction based upon a fluid flow rate through said catheter assembly, such that the forces resulting from the flow is substantially balanced or substantially zero fluid force in all directions (see paragraphs at column 8 through 9). Sandmore discloses that the distal end of the catheter is made of a material that is softer than a material of the proximal end (see paragraphs beginning at column 3). Further the Sandmore tubular structure is fully capable of enabling fluid flow rates in a range of approximately 0 to 40 ml/sec without failure of said tubular structure.

Concerning the size requirements of a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, and length of 1.22 mm (claims 17,19-20,42). Sandmore (or in the alternative Sandmore in view of Jones) discloses the claimed invention except for explicitly teaching the exact size parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a device with no greater or about 4 French, diameter approximately 0.305 mm or 0.33 mm, or a length of 1.22 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

It is examiners position that the size requirements, flow rate requirements, and balanced fluid forces are taught by Sandmore (or in the alternative Sandmore in view of Jones), but in the alternative it would have been an obvious modification to one having ordinary skill in the art at the time the invention was made, to have the specific size requirements (see discussion below), flow rate of approximately 0 to 40 ml/sec, and the balanced/zero fluid force function with the elastic restrictor and catheter assembly.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761